

BOARDS AND COMMISSIONS
Board of Nursing
(New Administrative Regulation)

201 KAR 20:474. Continuing approval and periodic evaluation of dialysis technician training programs.

RELATES TO: KRS 314.035, 314.131(1), 314.137

STATUTORY AUTHORITY: KRS 314.131(1), 314.137

NECESSITY, FUNCTION AND CONFORMITY: KRS 314.137 requires the board to promulgate administrative regulations to regulate dialysis technicians. This administrative regulation establishes the requirements for continued approval of dialysis technician training programs.

Section 1. Renal Dialysis Center Survey and Certification. (1) The board shall retain jurisdiction over Dialysis Technician Training Programs and may conduct site visits or other investigations into any allegation that may constitute a violation of 201 KAR 20:472 or 201 KAR 20:474. The board may conduct a site visit at any time, and may also conduct site visits when the Centers for Medicaid and Medicare Services (CMS) conducts a survey or site visit of the Renal Dialysis Center utilized by the Dialysis Technician Training Program.

(2) A Dialysis Technician Training Program shall notify the board regarding CMS site visits:

(a) Within thirty (30) days following the site visit that it has occurred; and

(b) Within ninety (90) days following the close of the site visit the Program shall forward all correspondence and reports from CMS concerning the site visit, any statement of deficiencies, subsequent plan of correction, and the continued approval certification.

Section 2. Dialysis Technician Training Program Evaluation. (1) To verify continued compliance with 201 KAR 20:472, the program shall submit progress reports or periodic supplemental reports, completed questionnaires, surveys, and other related documents as requested by the board.

(2) A dialysis technician training program shall perform a systematic review of the training program that results in continuing improvement. This process shall result in an evaluation report that is submitted to the board on an annual basis.

(3) Data collection for the evaluation report shall be on-going and shall reflect aggregate analysis and trending.

(4) The evaluation report shall include specific responsibilities for data collection methods, individuals or groups responsible, frequency of data collection, indicators of achievement, findings, and outcomes for evaluating the following aspects of the dialysis technician training program:

(a) Organization and administration of the dialysis technician training program;

(b) Curriculum;

(c) Teaching and learning methods including distance education;

(d) Faculty evaluation;

(e) Student achievement of program outcomes;

(f) Student completion rates;

(g) Student certification achievement rates; and

(h) Clinical resources.

(5) If a dialysis technician training program utilizes distance education for didactic instruction, it shall evaluate and assess the educational effectiveness of its distance education pro-

gram to ensure that the distance education is substantially comparable to face to face education.

(6) The evaluation report shall provide evidence that the outcomes of the evaluation process are used to improve the quality and strength of the dialysis technician training program.

Section 3. Voluntary Closure of a Dialysis Technician Training Program.

(1) A dialysis technician training program that intends to close shall submit written notification to the board at least six (6) months prior to the planned closing date.

(2) The Dialysis Technician Training Program may choose one (1) of the following procedures for closing:

(a) The Dialysis Technician Training Program shall continue to operate until the last class enrolled has completed training.

1. The program shall continue to meet the standards until all students enrolled have completed the program.

2. The official closing of the program shall be the date on the certificate of the last graduate.

3. The dialysis technician training program shall notify the board in writing of the official closing date.

(b) The dialysis technician training program shall close the program following the transfer of students to other approved dialysis technician training programs.

1. The program shall continue to meet the standards until all students have transferred.

2. The names of students who have transferred to approved programs and the date of the last student transfer shall be submitted to the board by the Renal Dialysis Center.

3. The date of the last student transfer shall be the official closing date of the program.

(3) Custody of records.

(a) The Dialysis Technician Training Program that continues to operate shall retain responsibility for the records of the students and graduates. The board shall be advised of the arrangement made to safeguard the records.

(b) The Dialysis Technician Training Program that ceases to exist shall transfer training logs and certificates of completion of each student and graduate to a third party vendor approved by the Council for Postsecondary Education for safekeeping.

Section 4. Continued Approval of a Dialysis Technician Training Program.

(1) To receive continued approval, a dialysis technician training program shall:

(a) File a completed Application for Dialysis Technician Training Program Approval;

(b) Submit an annual program evaluation summary report as required by Section 2(2) of this administrative regulation;

(c) Submit a list of current faculty including the name, title, and credential identifying the educational and professional qualifications of each instructor; and

(d) Pay a fee of \$1000.

(2)(a) The material required to be submitted by paragraph (1) of this section shall be submitted at least ninety (90) days prior to the end of the current approval period.

(b) If any of the material required to be submitted pursuant to paragraph (1) of this section is submitted less than ninety (90) days but more than thirty (30) days prior to the end of the current approval period, an additional fee of \$300 shall be charged. Nonpayment of this fee shall result in denial of the application for continued approval.

(c) If material required to be submitted pursuant to paragraph (1) of this section is submitted less than thirty (30) days prior to the end of the current approval period, the material shall not be accepted. The program shall lapse at the end of the current approval period and the renewal fee shall be forfeited.

(3) Continued approval shall be based on compliance with the standards established in 201 KAR 20:472 and this administrative regulation.

(4) Continued approval shall be granted for a two (2) year period.

(5) If a program fails to seek renewal of its approval status thirty (30) days prior to the end of the current approval period, the approval shall lapse at the end of the current approval period.

Section 5. Reinstatement of Dialysis Technician Training Programs.

(1) A program with lapsed approval shall cease all training activity until provided with written notice of the reinstatement of approval.

(2) A dialysis training program that has closed or that has a lapsed or withdrawn approval status may seek to reinstate approval as follows:

(a) File a completed Application for Dialysis Technician Training Program Approval;

(b) If applicable, file evidence of compliance with the requirements of any order issued by the board in accordance with Section 8 of this administrative regulation; and

(c) Pay a fee of \$1000.

Section 6. Site Visits. (1) A representative of the board may conduct a site visit at any time.

(2) The following situations may be cause for a site visit to determine if the standards of 201 KAR 20:472 and 201 KAR 20:474 are being met:

(a) Change of status by CMS or an accrediting body recognized by CMS;

(b) Providing false or misleading information to students or the public concerning the dialysis technician training program;

(c) A written complaint received from faculty, students, or the general public relating to a violation of 201 KAR 20:472 or 201 KAR 20:474;

(d) A change in physical facilities;

(e) Information received by the board that may indicate a violation of 201 KAR 20:472 or 201 KAR 20:474; and

(f) Failure to submit reports as required by 201 KAR 20:472 or 201 KAR 20:474.

Section 7. Action Following Site Visit. (1)(a) Following a site visit and prior to board consideration, a draft of the site visit report shall be made available to the program administrator for review and correction of factual data.

(b) The program administrator shall be available during the discussion of the report at the board committee to provide clarification.

(c) If the site visit results in a finding of non-compliance with 201 KAR 20:472 or 201 KAR 20:474 by the dialysis technician training program, a letter shall be sent to the program administrator regarding any requirements to be met.

(d) The board shall notify the dialysis technician training program of the time frame within which it shall meet the requirements. The board shall verify that the requirements have been met.

(2)(a) If the dialysis technician training program is unable to meet the requirements in the time set by the board, it may request additional time. The board, in its discretion, may grant or deny this request based on the rationale for the request.

(b) If the board denies the request for additional time, it shall begin the process established in Section 8 of this administrative regulation.

Section 8. Withdrawal of Approval. (1) In the event that the standards are not being met, the board shall send notice to the program administrator of the affected dialysis technician training program of its intent to withdraw approval. The notice shall be sent return receipt requested.

(2) When making this determination, the board shall consider the following factors:

- (a) The number and severity of the deficiencies;
- (b) The length of time in which the deficiencies have existed; and
- (c) Any exigent circumstances.

(3) Within thirty (30) days of receipt of the notice, the program administrator of the affected program may request an administrative hearing pursuant to KRS Chapter 13B. If an administrative hearing is not requested, program approval shall be withdrawn and the dialysis technician training program shall be closed. A closed program shall comply with section 3 of this administrative regulation.

(4)(a) If a program of nursing requests an administrative hearing, that hearing shall be held within sixty (60) days of the request.

(b) The hearing shall be held before a hearing officer designated by the board pursuant to KRS Chapter 13B.

(c) If the order of the board is adverse to the dialysis technician training program, the board may impose the following costs:

- 1. The cost of the stenographic services;
- 2. The cost of any expert witness, including travel;
- 3. Travel for other witnesses;
- 4. Document reproduction costs; and
- 5. The cost of the hearing officer which shall be \$400 per day.

(5)(a) The dialysis technician training program that has been closed shall assist a currently enrolled student to transfer to an approved dialysis technician training program.

(b) A dialysis technician training program that fails to assist students as required in this subsection shall be ineligible for reinstatement for at least one (1) year.

JESSICA WILSON, President

APPROVED BY AGENCY: April 15, 2021

FILED WITH LRC: May 18, 2021 at 1:10 p.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall be held on Monday, August 23, 2021 at 10:00 a.m. (EDT) in the office of the Kentucky Board of Nursing, 312 Whittington Parkway, Suite 300, Louisville, Kentucky. Individuals interested in being heard at this hearing shall notify this agency in writing five workdays prior to the hearing of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who wishes to be heard will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted until end of day (11:59 p.m., EDT) Tuesday, August 31, 2021. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person.

CONTACT PERSON: Morgan Ransdell, Kentucky Board of Nursing, 312 Whittington Parkway, Suite 300, Louisville, Kentucky 40222, phone (502) 429-3339, email Morgan.Ransdell@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person: Morgan Ransdell

- (1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes the requirements for continued approval of dialysis technician (“DT”) training programs.

(b) The necessity of this administrative regulation: This regulation is necessary pursuant to KRS 314.137(2).

(c) How this administrative regulation conforms to the content of the authorizing statutes: This regulation conforms to the content of KRS 314.137(2) by establishing standards for DT training programs.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This regulation will assist in the effective administration of KRS 314.021, as amended effective June 30, 2021, and KRS 314.137(2), by establishing standards for DT training programs.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: The fee increases set forth in this amendment are addressed below. This amendment: expands site visit authorization, including the option of agency participation during site visit conducted by the CMS to evaluate DT training program compliance with 201 KAR 20:472 and 201 KAR 20:474; identifies specific criteria for DT training program annual reports, including student completion and certification rates; requires six month notice of voluntary closure, and provides a teach out option or an option under which current trainees transfer to other programs; requires applications and supporting documents seeking to continue approval status to be submitted more than 30 days prior to the expiration of approval status, and imposing a \$300 fine when such materials are submitted less than 90 days prior to the expiration of approval status; increases the fee applicable to an active program’s application for continued approval status from \$800 to \$1,000; states that lapsed programs must cease all training activity; increases the fee required when a lapsed program applies for reinstatement of approval status from \$950 to \$1,000; clarifies the circumstances under which a site visit may occur, and provides for the recovery of hearing costs in cases where a hearing disposition under KRS Chapter 13B is adverse to the DT training program.

(b) The necessity of the amendment to this administrative regulation: The regulation is necessary for the oversight of the practices and training of dialysis technicians, as required by KRS 314.021 (amendment effective June 30, 2021), and KRS 314.137(2).

(c) How the amendment conforms to the content of the authorizing statutes: The regulation conforms to the content of the authorizing statutes, KRS 314.131(1) and KRS 314.137(2), by establishing appropriate standards for DT training programs in order to protect and safeguard the health and safety of the citizens of the Commonwealth of Kentucky.

(d) How the amendment will assist in the effective administration of the statutes: The regulation will assist in the effective administration of KRS 314.021 and KRS 314.137(2), by establishing standards for DT training programs.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: As of April 8, 2021, there were 712 dialysis technicians with a current and active Kentucky DT credential. There are currently seven DT training programs that are located and licensed in Kentucky. The Kentucky Board of Nursing, the seven Kentucky DT training programs in the Commonwealth, and all renal dialysis organizations that provide dialysis services within the Commonwealth will all be affected by the repeal of 201 KAR 20:470 and the promulgation of 201 KAR 20:474. The two largest renal dialysis organizations in Kentucky are Davita, Inc., and Fresenius Medical Care North America.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: Each existing DT training program and renal dialysis organization in Kentucky will need to evaluate their programmatic requirements and standards in light of 201 KAR 20:472 and 201 KAR 20:474, as the standards for program approval are also relevant to the evaluation of existing programs pursuant to 201 KAR 20:472 Section 2 and 201 KAR 20:474 Section 2(1). DT training program annual reports will be required to address eight specific factors, including student completion and certification rates; and programs seeking voluntary closure will be required to provide notification to the board 6 months prior to closure, rather than 30 days prior to closure as specified in 201 KAR 20:470.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): The fee required when an active program applies for continued approval status has been increased by \$200, from \$800 to \$1,000, and the fee required when a lapsed program applies for reinstatement of approval status has been increased by \$50, from \$950 to \$1,000. The existing fees are not adequate to cover the staff cost associated with the provision of staff guidance to DT training programs, and the review of the program's application and associated submissions, which requires 15-20 hours of work, on average, when a DT program that previously held approval status seeks continued approval status or reinstatement. The hourly salary inclusive of all benefits of the KBN employee who conducts program review is \$69.98.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Compliance with 201 KAR 20:474 allows DT training programs to operate lawfully and avoid closure.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: Implementation of 201 KAR 20:474 will result in a larger commitment of staff work hours, primarily due to the anticipated need for collaboration with existing programs that seek guidance with regard to expanded annual reporting requirements; however, it is impossible to calculate the precise cost of the additional demands upon staff that are anticipated. Agency costs associated with implementation of 201 KAR 20:474 are further addressed below in Section 3(c) of the Fiscal Note on State or Local Government.

(b) On a continuing basis: Following implementation of 201 KAR 20:474, the agency cost associated with 201 KAR 20:474 will be attributable entirely to the work hours associated with coordination with previously approved DT training programs, associated document review, and any resulting enforcement activity. Agency costs associated with the continued enforcement 201 KAR 20:474 of are further addressed below in Section 3(d) of the Fiscal Note on State or Local Government.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: Fees paid by DTs and DT training programs are the primary source of funding for implementation of 201 KAR 20:474.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: The fee required when an active program applies for continued approval status has been increased by \$200, from \$800 to \$1,000, and the fee required when a lapsed program applies for reinstatement of approval status has been increased by \$50, from \$950 to \$1,000. These increases are implemented to address an existing inequity, as the review of a DT training program

that previously held approval status, including communication with the program and review of all submissions, requires 15-20 hours of work, on average. The hourly salary, inclusive of all benefits, of the KBN employee who conducts program review is \$69.98. The existing fees of \$800 for active DT training programs seeking continued approval status, and \$950 reinstatement fee, were determined immediately following passage of HB 184 in 2001, which is when the Kentucky Board of Nursing was first assigned regulatory authority over DTs and DT training programs. In the twenty years since, the fee has remained static, while personnel costs have increased.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: The fee required when an active program applies for continued approval status has been increased by \$200, from \$800 to \$1,000, and the fee required when a lapsed program applies for reinstatement of approval status has been increased by \$50, from \$950 to \$1,000.

(9) TIERING: Is tiering applied? Tiering was not applied to 201 KAR 20:474, as the regulation treats all DT training programs similarly.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

(1) What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Kentucky Board of Nursing.

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 314.131 and KRS 314.137.

(3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? In FY2020, KBN revenues from receipts associated with the DT program were \$15,106. For FY2021, revenues from receipts associated with the program are \$7,973 to date. The precise amount of anticipated FY2022 DT program receipts is not known, but is expected to be approximately \$15,000. The bulk of DT program receipts are attributable to DT renewal fees. These receipts are not consistent year to year, in light of the two-year DT renewal cycle. The fee increase for renal dialysis organizations seeking continued or reinstated program approval will not have a significant impact on agency receipts, as there are only seven DT training programs in Kentucky currently, and the Board does not anticipate a significant number of new program applications.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? As there are only seven DT training programs that currently hold approval status, and as the agency is not anticipating a significant number of new DT training program applications, the fee increases specified in 201 KAR 20:474 will not have a substantial impact on revenues.

(c) How much will it cost to administer this program for the first year? The agency expended \$26,446.02 for the DT program in FY2020. The FY2021 budget for the DT program is \$26,600, and \$25,331.69 has been expended associated with the DT program to date in the current fiscal year. Board staff anticipates a similar level of expenditure in FY2022.

(d) How much will it cost to administer this program for subsequent years? Board staff anticipates that DT program expenditures will rise from a baseline cost of \$26,600 in future years,

as personnel costs rise; however, the precise impact of possible personnel cost increases have not been determined.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation: As there are only seven DT training programs that currently hold approval status, and as the agency is not anticipating a significant number of new DT training program applications, the anticipated fiscal impact of the fee increases specified in 201 KAR 20:474 is small, amounting to \$200 for each application for continued approval status, and \$50 for each reinstatement application.